K070886

APR 26 2007

# 510(k) SUMMARY
# SUMMARY OF SAFETY AND EFFECTIVENESS
# FOR
# MeroGel Injectable Bioresorbable Dressing

| | |
|---|---|
| **510(k) Owner** | Medtronic Xomed, Inc<br>6743 Southpoint Drive North<br>Jacksonville, Florida 32216-0980 USA<br>904-296-9600<br>904-296-2386 (FAX) |
| **Contact Name** | Jayme Wilson<br>Senior Regulatory Affairs Specialist<br>Medtronic Xomed, Inc |
| **Date Summary Prepared** | April 24, 2006 |
| **Proprietary Name** | MeroGel Injectable Bioresorbable Dressing (Final name TBD) |
| **Common Name** | Polymer, Ear, Nose and Throat, Synthetic, Absorbable |
| **Classification Name** | Ear, nose and throat synthetic polymer material (21 CFR 874.3620, Product Code NHB, Class II) |

**Marketed device claiming equivalence to**

MeroGel Injectable Bioresorbable Stent is equivalent to Genzyme Corporation's Sepragel™ ENT Nasal/Sinus and Otologic Dressing, K043035 and Medtronic Xomed's MeroGel™ Otologic Pack, K001148.

**Device Description**

MeroGel Injectable Bioresorbable Stent is a sterile, transparent, viscoelactic, bioresorbable gel composed of cross-linked polymers of hyaluronic acid. The MeroGel Injectable Bioresorbable Stent fills ENT cavities following surgery or trauma to keep to tissues or structures separate during the healing process. During this time, the tamponade effect helps control minimal bleeding normally associated with routine ENT surgery. MeroGel Injectable leaves the site of placement by natural elimination, or it may be aspirated from the cavity earlier at the discretion of the physician.

**Intended Use**

MeroGel Injectable Bioresorbable Stent is a space occupying gel stent intended to separate and prevent adhesions between mucosal surfaces, help control minimal bleeding following surgery or nasal trauma, and act as an adjunct to aid in the natural healing process.

**Indications for Use**

MeroGel Injectable Bioresorbable Stent is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery. The device is indicated following nasal/sinus surgery or trauma to prevent lateralization of the middle turbinate and nasal adhesions during the post operative period.

## Comparison to Marketed Devices

| | MeroGel™ Injectable Bioresorbable Stent<br>Medtronic Xomed<br>PROPOSED | Sepragel™ ENT Nasal/Sinus and Otologic Dressing<br><br>Genzyme Corporation<br>K043035 | MeroGel™ Otologic Pack<br><br>Medtronic Xomed<br>K001148 |
|---|---|---|---|
| Device Name | ENT synthetic polymer material | ENT synthetic polymer material | ENT synthetic polymer material |
| Product Code | 77NHB | 77KHJ | 77KHJ |
| Intended Use/Indication | MeroGel Injectable Bioresorbable Stent is a space occupying gel stent intended to separate and prevent adhesions between mucosal surfaces, help control minimal bleeding following surgery or nasal trauma, and act as an adjunct to aid in the natural healing process. MeroGel Injectable Bioresorbable Stent is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery. The device is indicated following nasal/sinus surgery or trauma to prevent lateralization of the middle turbinate and nasal adhesions during the post operative period. | For use in patients undergoing nasal/sinus surgery as a space-occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the postoperative period. The device is also indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty and, stapes and mastoid surgery | MeroGel Otologic Pack is a space occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding and act as an adjunct to aid in the natural healing process. MeroGel Otologic Pack is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery. |
| Material | Derivative hyaluronic acid | Derivative hyaluronic acid | Derivative hyaluronic acid |
| Bioresorbable | YES | YES | YES |
| Sterile | YES | YES | YES |
| Product Matrix | Gel in a syringe | Gel in a syringe | Non-woven pad in a protective folded sheet |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Xomed
c/o Jayme Wilson
6743 Southpoint Drive North
Jacksonville, Florida 32216-0980

APR 26 2007

Re: K070886
Trade/Device Name: MeroGel™ Injectable Bioresorbable Stent
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear Nose & Throat Synthetic Polymer Material
Regulatory Class: II
Product Code: NHB
Dated: March 29, 2007
Received: March 30, 2007

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K070886

Device Name: MeroGel Injectable Bioresorbable Stent (Final name to be determined)

Indications for Use:

MeroGel Injectable Bioresorbable Stent is a space occupying gel stent intended to separate and prevent adhesions between mucosal surfaces, help control minimal bleeding following surgery or nasal trauma, and act as an adjunct to aid in the natural healing process.

MeroGel Injectable Bioresorbable Stent is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery. The device is indicated following nasal/sinus surgery or trauma to prevent lateralization of the middle turbinate and nasal adhesions during the post operative period.

| Prescription Use X | AND/OR | Over-The-Counter Use |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | | (21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K070886

Prescription Use X
(Per 21 CFR 801.109)